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European Patent Office
Office européen des brevets



(11) Publication number:

0 640 356 A1

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: **94108489.9**

(51) Int. Cl.⁶: **A61M 16/12**

(22) Date of filing: **01.06.94**

(30) Priority: **22.07.93 SE 9302477**

(43) Date of publication of application:
01.03.95 Bulletin 95/09

(84) Designated Contracting States:
AT CH DE ES FR GB IT LI NL SE

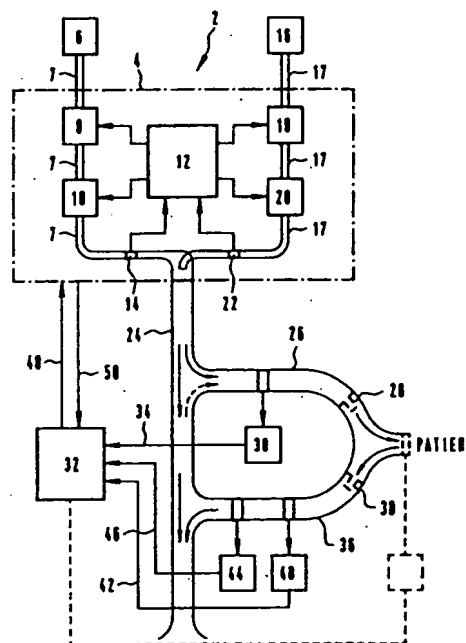
(71) Applicant: **Siemens Elema AB**
Röntgenvägen 2
S-171 95 Solna 1 (SE)

(72) Inventor: **Olsson, Sven-Gunnar**
Villa Fortuna
S-232 00 Arlöv (SE)
Inventor: **Rydgren, Göran**
Strandängsvägen 4
S-230 44 Bunkflostrand (SE)
Inventor: **Larsson, Anders**
Poppelvägen 12
S-244 00 Kävlinge (SE)

(54) **Device for supplying breathing gas.**

(57) The invention relates to a device (2) which supplies breathing gas mixed with an additive gas to a patient for pulmonary diagnosis or pulmonary treatment. The device (2) comprises a gas mixing unit (4) through which a relatively large flow of breathing gas is achieved from a first gas source (6) through a first pressure regulator (8) and a second pressure regulator (10). The breathing gas passes through a connecting tube (24) from which the patient can breathe spontaneously through an inspiration tube (26), thereby inhaling air from the connecting tube (24). Expired gas passes via an expiration tube (36) to the connecting tube (24). Additive gas is supplied from a separate gas source (16) via a second pressure regulator (18) and a second flow regulator (20). The additive gas is supplied in a flow which is considerably smaller than the flow of breathing gas, whereby a very small but accurate concentration of the additive gas can be achieved in the breathing gas. The large flow prevents a reactive additive gas from reacting before being supplied to the patient.

FIG 1



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The present invention relates to a device for supplying a breathing gas containing a predetermined concentration of a specific additive gas to the lungs of a living creature, comprising an inspiration tube through which breathing gas and additive gas are delivered to the lungs, an expiration tube through which expired gas is carried away from the lungs, a first adjustable gas source for supplying breathing gas to the inspiration tube and a second adjustable gas source for supplying at least the additive gas to the inspiration tube.

In the diagnosis of pulmonary function and treatment of the lungs, having a patient spontaneously breathe a breathing gas containing a predetermined concentration of a specific additive gas may be appropriate. The additive gas could be e.g. nitric oxide, NO, nitrous oxide N_2O , or sulphur hexafluoride, SF_6 . For example, NO could be used for relaxing the smooth muscle in blood vessels and bronchi or for determining the diffusion capacity of the lungs. N_2O can be used for determining the blood's rate of flow through the lungs, and SF_6 could be used for determining the functional residual capacity (FRC) of the lungs. Measurement of pulmonary pressure also supplies a measure of the resistance to flow through the lungs.

Certain additive gases, such as NO, react strongly with e.g. oxygen and must therefore be added to breathing gas close to the patient so the additive gas is fed down into the lungs without having time to combine chemically with oxygen and form NO_2 . In order to simplify the supplying of small amounts, one or two ppm, of an additive gas, the additive gas is usually mixed with some other gas, such as N_2 , in a higher concentration, e.g. 100 ppm. This gas mixture is then added to the flow of breathing gas at a flow rate which is a predetermined fraction of the flow of breathing gas in order to produce the correct concentration. So gas is supplied in two stages.

In a European patent application no. 92108636.9 is described a ventilator which can control very small flows. An accurate concentration of NO or some other additive gas can be delivered to a patient's lungs with such a ventilator. However, the ventilator is complex.

One object of the invention is to achieve a device which can supply a breathing gas containing a specific additive gas to the lungs, simply and reliably, in such a way that active additive gases do not have time to react with other gases before passing down into the lungs.

The object is achieved with a device in accordance with the invention in that the first gas source supplies a continuous flow of the breathing gas, the second gas source supplies a continuous flow of the additive gas, a connecting tube is connected to the gas sources and a gas evacuation system,

whereby the gas sources supply the breathing gas and the additive gas for mixing in the connecting tube, mixed gas passes through the connecting tube to the gas evacuation system, and the inspiration tube is connected to the connecting tube between the gas sources and the gas evacuation system, whereupon breathing gas and additive gas pass through the inspiration tube to the lungs at inhalation.

The continuous flow of breathing gas can advantageously be relatively large, e.g. 20 l/min. The additive gas, which could be e.g. NO, diluted to 1000 ppm in N_2 , is supplied at a slower flow rate, e.g. 20 ml/min up to 2 l/min. When additive gas is added to the breathing gas flow, the gases mix and result in a concentration of additive gas, NO in this instance, of e.g. 1 to 100 ppm. However, the continuous flow of mixed gas must be at least as large as the patient's minute volume. When the patient inhales, air in the connecting tube is drawn in through the inspiration tube to the lungs. Because of the large flow of gas, the additive gas does not have time to react with other gases before being drawn into the lungs. Relatively large flows are also easier to measure and control than small flows, so a desired concentration can therefore be attained by accurate control of flows. In principle, no gas meters are necessary. If the patient takes a breath so deep that the amount of gas supplied is inadequate, gas downstream from the inspiration tube's connection to the connecting tube is sucked back and pass into the inspiration tube. Here, the connecting tube also serves as a reservoir for breathing gas and additive gas. This device also ensures that the patient always inspires a fresh gas mixture. Surplus additive gas which is not inspired by the patient is fed into the ambient atmosphere or into some kind of collection vessel.

Here, it would be advantageous if the device were devised so the expiration tube were connected to the connecting tube downstream from the inspiration tube's connection to the connecting tube.

Only a gas evacuation system would then be needed to dispose of both surplus gas and expired gas. It would be advantageous if the connection between the expiration tube and the connecting tube were placed at distance far enough away from the connection between the inspiration tube and the connecting tube to prevent any expired air from being sucked up to the connection between the inspiration tube and the connecting tube.

It would be advantageous if the device were devised so a first gas meter is connected to the inspiration tube in order to measure the concentration of additive gas. This would enhance patient safety. The gas meter could be connected to an alarm or to the second source of gas in order to

reduce or cut off the flow of additive gas if that flow became too large. The gas meter could also be used in conjunction with various diagnostic investigations of the lungs.

In conjunction with both treatment and diagnostic examinations, it would be advantageous if the device were devised so a second gas meter is connected to the expiration tube in order to measure the concentration of additive gas. The body's uptake of additive gas can be determined when the concentration of both inspired and expired additive gas is measured. This can be performed e.g. in determining the blood's rate of flow in the lungs by determining the body's uptake of N_2O . The second gas meter can also be used for e.g. determining the functional residual capacity (FRC) of the lungs.

A refinement of the device is achieved in accordance with the invention in that the first source of gas comprises a fan for generating the predetermined, continuous flow of breathing gas, whereby the breathing gas consists of ambient air.

The entire device can be made compact and suitable for treatment of patients at home or during transport when a fan is utilized to create the large flow of breathing gas.

It would be advantageous if the additive gas were one of the gases NO , N_2O , SF_6 or an inert gas. These gases are well-known and used both in determinations of pulmonary function and in treatment of the lungs.

A gas mixture according to the simultaneously submitted Swedish patent application no. can also be used advantageously in the present device. Here, SF_6 is employed as a trace gas, whereby the concentration of the additive gas can be determined by adding an exact mixture of SF_6 and additive gas and then measuring the concentration of SF_6 . When a trace gas, such as SF_6 , is used, determining the concentration of the additive gas by measuring the concentration of trace gas on the expiration side of the device also becomes possible. The gas meter on the inspiration side then becomes unnecessary. The gas meters can also be calibrated before a patient is connected to the device by passing the desired mixture of breathing gas and additive gas through the gas meters. If a faulty gas mixture is connected, the fault will be so large that even a non-calibrated gas meter will indicate that something is wrong. If the additive gas is an inert gas, the concentration of the trace gas measured must be corrected for the presence of inert gas in the atmosphere and, thus, in the breathing mixture.

Two embodiments of the device according to the invention will now be described in greater detail, referring to two figures in which

FIG. 1 shows a first embodiment of a device according to the invention, and

FIG. 2 shows a second embodiment of a device according to the invention.

The device 2 in FIG. 1 comprises a gas mixing unit 4 which receives a breathing gas from a first gas source 6 via a gas tube 7. The breathing gas passes a first pressure regulator 8 and a first flow regulator 10 in order to achieve a predetermined pressure and flow which are controlled by a control unit 12. A first flow meter 14, which sends a measurement signal to the control unit 12, is also located in the gas tube 7. The control unit then regulates the pressure regulator 8 and the flow regulator 10 on the basis of the measured flow.

The gas mixing unit 4 adds an additive gas from a second gas source 16 through a gas tube 17. The additive gas passes a second pressure regulator 18 and a second flow regulator 20, both controlled by the control unit 12 on the basis of the flow measurement signals measured by a second flow meter 22. The additive gas could consist of e.g. NO , diluted with N_2 . A connecting tube 24 runs from the gas mixing unit 4 to a gas evacuation system. Breathing gas and the additive gas are mixed in the connecting tube 24. Here, breathing gas is added at a relatively large rate of flow, e.g. 20 l/min, whereas additive gas is added at a smaller rate of flow, e.g. 20 ml/min. With a predetermined concentration of 1000 ppm of NO in the second gas source 16, the gas in the connecting tube 24 will contain 1 ppm NO . The gas mixture passes from the connecting tube 24 in an inspiration tube 26 through a first check valve 28 to a patient who draws gas from the connecting tube 24 during spontaneous breathing, as indicated by an arrow in the figure. If the patient takes a breath so deep that total flow is inadequate, gas is drawn downstream from the connection between the inspiration tube 26 and the connecting tube 24, as designated with a dashed arrow.

A first gas meter 30 for measuring the concentration of NO in the breathing gas is also located in the inspiration tube 26. The measurement value is sent to an analyzer 32 via a first signal line 34.

When the patient exhales, expired gas passes through the expiration tube 36 via a second check valve 38. In this way, the check valves 28, 38 control the direction of flow through the inspiration tube 26 and the expiration tube 36. The expiration tube 36 then connects to the connecting tube 24, and expired gas passes to the gas evacuation system with any surplus gas from the gas mixing unit 4. Evacuation can be into ambient air or a collection vessel of some kind in which one or more different gases can be absorbed.

A second gas meter 40, which measures the concentration of NO in expiration air and sends a measurement signal to the analyzer 32 via a sec-

ond signal line 42, is located in the expiration tube 36. The uptake of NO in the body can be determined and, thus, the diffusion capacity of the lungs, on the basis of the concentration of inspired NO and the concentration of expired NO.

A third flow meter 44 measures flow in the expiration tube 36 and sends the measurement value to the analyzer 32 via a third signal line 46. In addition to calculating diffusion capacity, the analyzer 32 can also include functions such as monitoring, alarm and control. The analyzer 32 can communicate with the gas mixing unit 4 via a fourth signal line 48 and a fifth signal line 50.

The third flow meter 44 can be located in the Y piece, as suggested in the figure with a dashed line. In this manner, the flow of both inspired and expired gas can be measured with a single flow meter.

In FIG. 2 is shown an alternative version of a device according to the invention. The device 52 comprises a gas mixing unit 54 supplied with a breathing gas from a first gas source 56 via a gas tube 58. In this instance, the first gas source 56 consists of ambient air, and the predetermined pressure and flow of breathing gas is generated by a fan 60. The fan is controlled by a control unit 62 on the basis of measurement signals from a first flow meter 64. An additive gas is supplied, as in the preceding embodiment, from a second gas source 66 through a gas tube 68 to a gas mixing unit 54. The additive gas passes a pressure regulator 70 and a flow regulator 72 so a specific pressure and flow are attained. The pressure regulator 70 and the flow regulator 72 are controlled by the control unit 62 on the basis of measurement signals from a second flow meter 74.

The breathing gas and additive gas are mixed in a connecting tube 76 before passing through an inspiration tube 78 to a patient. As in the preceding instance, a first check valve 80 is located in the inspiration tube 78.

In this instance, a gas meter 82 measures the concentration of NO in inspiration gas and sends the measurement signal to the gas mixing unit 54 via a signal line 84. In this instance, treatment is intended for a patient with high vascular resistance in the pulmonary alveoli. A small amount of NO, less than 1 ppm, relaxes smooth muscle in the vessels, and the flow of blood increases past the alveoli.

Expiration gas passes from the patient via an expiration tube 86 through a second check valve 88 out to the connecting tube 76 and on to evacuation. As in the preceding instance, evacuation can be into ambient air or special collection vessels.

The invention is not limited to the described embodiments. Other gases, such as SF₆ and He, can be used for different diagnostic or therapeutic

purposes. The device 52 according to the second embodiment can also comprise a gas meter and a flow meter on the expiration side and an analyzer for calculating various functions. In the corresponding manner, the device 2 according to the first embodiment can comprise a fan for generating a flow of breathing gas from ambient air. Other combinations of embodiments are also possible within the scope of the invention.

For example, the concentration of NO can be determined by adding an exact mixture of SF₆ and NO and measuring the concentration of SF₆. Here, the SF₆ concentration can be determined solely on the expiration side, whereby the flow of breathing gas can pass unimpeded to the patient.

In instances in which only a specific concentration of additive gas is to be supplied by the device, the device can be devised to supply a fixed flow from the respective gas source. The respective flow is periodically calibrated, and flows do not have to be measured or regulated. The device would thereby be simpler to make.

Even simpler regulation can be used if a somewhat less accurate concentration is permissible. For example, the large flow of breathing gas can be kept constant, and only the flow of additive gas is regulated. The simplest way to achieve this is by manual regulation. The NO concentration in the mixed gas can be determined for this purpose e.g. by measurement of the trace gas SF₆ and used for regulation.

Providing the device with a plurality of gas sources and gas tubes to the connecting tube is also possible. For example, oxygen, air, SF₆ and NO can be supplied from four different gas sources and mixed in the connecting tube in the same way shown in the figures. One alternative is to supply oxygen from a separate source with a fan generating a flow of atmospheric air through the connecting tube.

Claims

1. A device (2, 52) for supplying a breathing gas containing a predetermined concentration of a specific additive gas to the lungs of a living creature, comprising an inspiration tube (26; 78) through which a breathing gas and an additive gas are delivered to the lungs, an expiration tube (36; 38) through which expired gas is carried away from the lungs, a first adjustable gas source (6, 8, 10; 56, 60) for supplying the breathing gas to the inspiration tube (26; 78) and a second adjustable gas source (16, 18, 20; 66, 70, 72) for supplying at least the additive gas to the inspiration tube (26; 78), characterized in that the first gas source (6, 8, 10; 56, 60) supplies a continuous

flow of the breathing gas, the second gas source (16, 18, 20; 66, 70, 72) supplies a continuous flow of the additive gas, a connecting tube (24; 76) is connected to the gas sources (6, 8, 10, 16, 18, 20; 56, 60, 66, 70, 72) and a gas evacuation system, whereby the gas sources (6, 8, 10, 16, 18, 20; 56, 60, 66, 70, 72) supply the breathing gas and the additive gas for mixing in the connecting tube (24; 76), mixed gas passes through the connecting tube (24; 76) to the gas evacuation system and the inspiration tube (26; 78) is connected to the connecting tube (24; 76) between the gas sources (6, 8, 10, 16, 18, 20; 56, 60, 66, 70, 72) and the gas evacuation system, whereupon breathing gas and additive gas pass through the inspiration tube (26; 78) to the lungs during inhalation.

mixed gas is at least as large as the living creature's minute volume.

2. A device according to claim 1, **characterized in that** the expiration tube (36; 86) is connected to the connecting tube downstream from the inspiration tube's (26; 78) connection to the connecting tube (24; 76). 5
3. A device according to claim 1 or 2, **characterized in that** a first gas meter (30; 82) is connected to the inspiration tube (26; 78) in order to measure the concentration of additive gas. 10
4. A device according to any of the above claims, **characterized in that** a second gas meter (40) is connected to the expiration tube (36) in order to measure the concentration of additive gas. 15
5. A device according to any of the above claims, **characterized in that** the first gas source (56, 60) comprises a fan (60) for generating the predetermined, continuous flow of breathing gas, whereby the breathing gas consists of ambient air. 20
6. A device according to any of the above claims, **characterized in that** the additive gas consists of any of the gases NO, SF₆, N₂O or an inert gas. 25
7. A device according to claim 6, **characterized in that** when the additive gas consists of NO, an inert gas or N₂O, an exact mixture of the additive gas and SF₆ is used, whereby the SF₆ concentration is measured in order to determine the concentration of the additive gas. 30
8. A device according to any of the above claims, **characterized in that** the continuous flow of 35

FIG 1

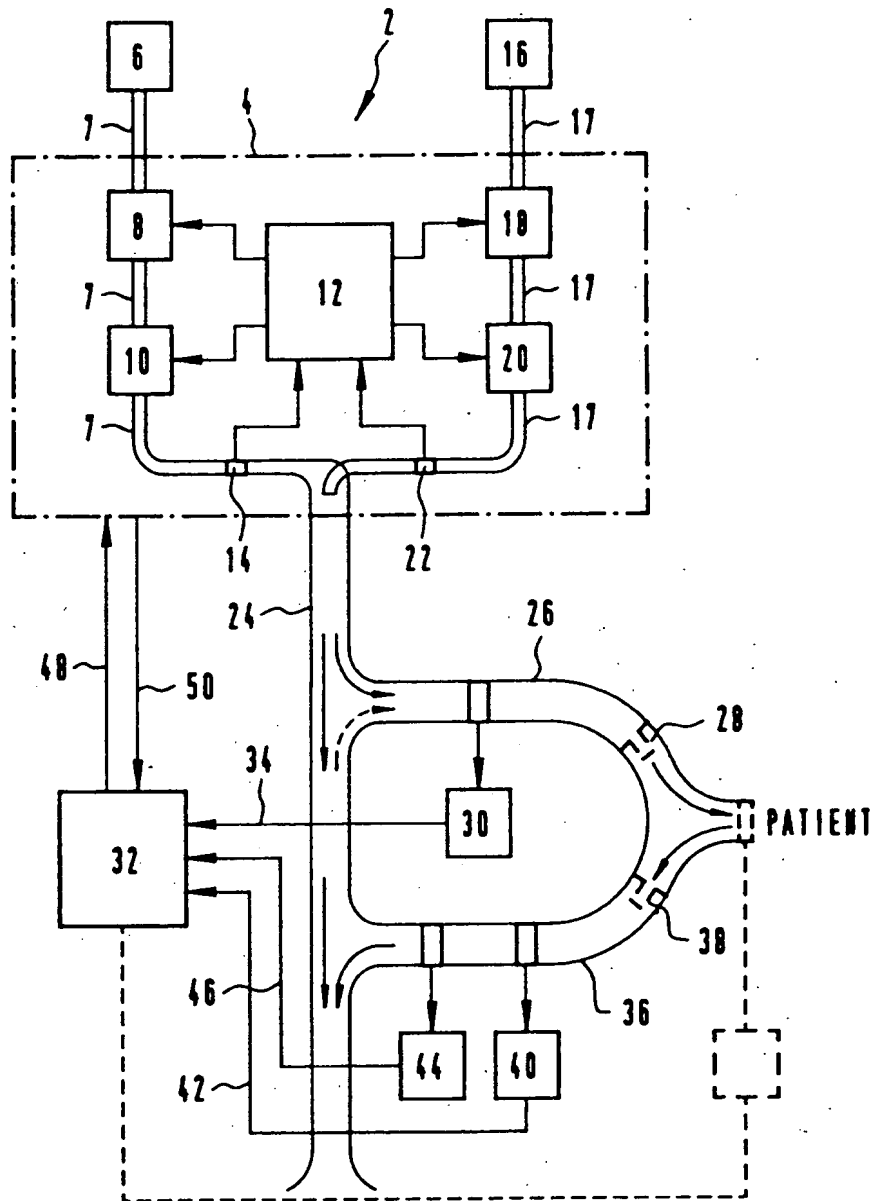
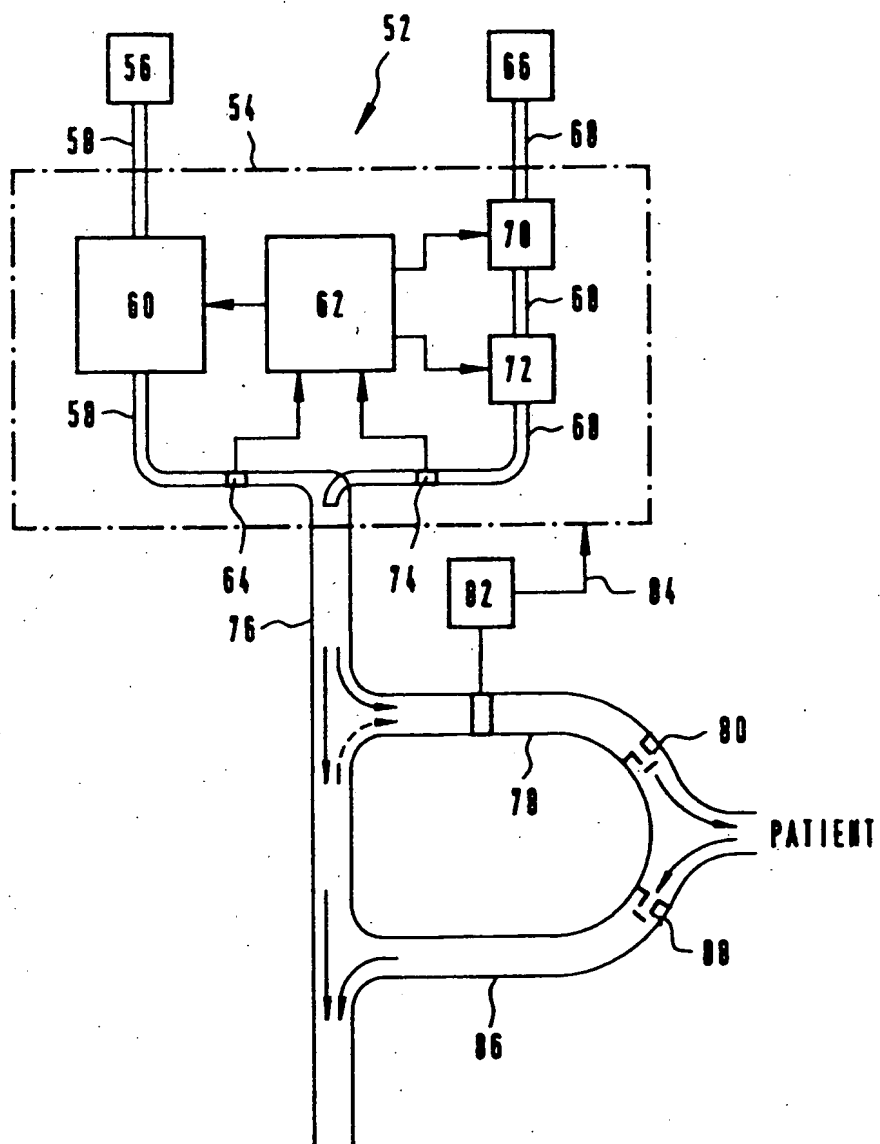


FIG 2





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 94 10 8489.9
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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP, A2, 0149722 (DRÄGERWERK AKTIENGESELLSCHAFT), 31 July 1985 (31.07.85) * figure 1 *	1,3,8	A61M 16/12
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X	EP, A2, 0166305 (GAMBRO ENGSTRÖM AB), 2 January 1986 (02.01.86)	1-5,8	
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X	US, A, 4903693 (YASUE), 27 February 1990 (27.02.90) * figure 2 *	1-5,8	

			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
STOCKHOLM		31 October 1994	ANETTE HALL
CATEGORY OF CITED DOCUMENTS			
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